

[\*\*\*Hospital letter head\*\*\*]

Local lead investigator: [\*\*\*local\_lead\*\*\*]

**ISARIC/WHO Clinical Characterisation Protocol**

**INFORMATION SHEET FOR PARENT/GUARDIAN**

**For parents or guardians of all children and young people under 16 years old, and those aged 16 years to 18 years who are unable to give their own consent for any reason.**

**VIRAL HAEMORHAGIC FEVER INFECTION**

**04 March 2016, Version 7.2**

The International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) in collaboration with the World Health Organization (WHO) are undertaking a research study involving people with severe infections including the Viral Haemorrhagic Fever Ebolavirus.

We are asking you about the participation of a child or young person who is below the legal age at which they can consent to participate in research. We are approaching you because we understand that you are the parent or legal guardian of that child or young person (hereafter referred to as your child). Please declare now if you are not the parent or legal guardian of this child.

Where possible, we will also give your child the opportunity to express his/her views and assent to participate.

Before you decide it is important for you to understand why the research is being done and what it would involve for your child. Please take time to read this information carefully. One of our team will go through the information with you. Please ask us if there is anything that is not clear or if you would like more information and time to decide. Your decision is completely voluntary. The decision you make will not affect your child’s care or treatment in any way.

**What is the study about?**

Infectious diseases affect millions of people around the world every year. Most cases are mild, but some people become very unwell. There is a great deal that we do not understand about existing infections, and new infectious diseases continue to appear. This research study will gain important information about VHF infection so we can try to find better ways to manage and treat them in the future.

**What will happen if the patient takes part in this study?**

We will first collect information from your child routine clinical records such as your child’s signs and symptoms, medications that he/she is taking, and the results of any blood test and laboratory results that doctors have ordered when hospitalise. This will happen every day while the participant is in hospital.

If you agreed, samples will be collected which are in addition to what would normally be collected for your child's medical care..

On some days extra blood will be collected for research analysis. This would only be taken when blood is being taken for clinical reasons, and then only with the approval of the attending clinicians. Your child will never have additional venesection (blood draws) taken only for research while in isolation.

The extra blood collected will be at most 15mls (3 teaspoons) on any day.

After your child leaves the isolation unit they may have additional blood samples taken only for research.

We are asking for this extra blood for research to be collected within the first 24hours of admission, then every second day over the next eleven days, and then once every week for as long as you are unwell up to a maximum of 100 days. We will also invite your child to go to a hospital or clinic convenient to you in 3 months and then again at 6 months to have one blood sample taken.

When any samples of blood, urine, stool or respiratory secretions are taken for normal care, and if there is any sample leftover after the tests requested by your doctors are done, we will store what is leftover for research purposes.

**What will happen to the samples and information?**

All information about your child will be kept confidential – anonymised - by those working on this study, your child’s name will not be used in any reports about this study. The results of the study will be shared as quickly as possible with health authorities, and doctors to help them treat patients with VHF Ebolavirus.

If samples are taken, we will use the blood samples to look at how the body fights the infection and how treatments given to your child work in the body. We will also use the blood sample to analyse your child's DNA. We will examine your child's DNA together with DNA from many other people to try to find out what makes some people more likely to get an infection. Some of the tests may be done in different countries.

All information about your child will be handled in confidence and only the people responsible for your child's care and for this study will know that your child was a part of the study. We will review your child's medical records and keep limited information about your child on a secure file. All information and samples will be labelled only with a number so that they cannot be directly linked to him/her personally. With your permission, we would also like to store your child's samples and use them for future ethically approved medical research. The data and samples collected during this study may be looked at by regulatory authorities, authorized individuals from University of Oxford, from the NHS Trust(s) or public health agencies.

Your child’s GP will be informed of he/she is taking part in this study.

**Are there any benefits to taking part in this study?**

There is no benefit to you or your child. The information gained from this study may not be available in time to affect your child's care. Any results available while your child is in hospital will be given to his/her treating doctor. The information we learn may help in caring for other patients in the future.

**What are the risks of being in the study?**

If your child takes part in the study and only clinical data is collected from the routine medical records there is a minimum risk, all information will be used anonymously (no one will know that this belonged to your child).

If agreed to collect samples, being a part of this study means that more samples will be taken than are needed for normal care. Whenever possible these samples will be taken at the same time as regular samples to reduce the extra procedures. There is a risk of pain or irritation when samples are taken.

When DNA testing is done, there is a small chance that the results will show a genetic condition that could affect your child's future health. Since the tests will be conducted anonymously, no-one on the study team will know that such a result applies to your child, and in any case there is usually considerable uncertainty about the implications of any research DNA test result for individual health. For these reasons we would not attempt to identify your child or inform your and your child of any results from DNA testing.

**Who is responsible and what if something goes wrong?**

The research is organised by the University of Oxford with the support of collaborators at this hospital, none of who will benefit financially from the study It has been reviewed and given a favourable opinion by Oxford C Research Ethics Committee (Ref 13/SC/0149).

The University has arrangements in place to provide for harm arising from participation in the study for which the University is the Research Sponsor. NHS indemnity operates in respect of the clinical treatment with which you are provided. [\*\*\*insert sponsor and contact details\*\*\*]

**Can I request that I be withdrawn from the study at any point?**

Yes, you and your child can withdraw at any time without giving a reason and without affecting your child's care. Any data and samples that have not already been analysed can be withdraw/destroyed anytime you request it.

**What if I have any problems or would like further information about the study?**

If you would like more information about the study you can contact the Lead Investigator in your hospital [\*\*\*local\_lead\*\*\*] or telephone the study coordinator’s office on [\*\*\*phone\_number\*\*\*].